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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.            | CONFIRMATION NO.       |
|---|-------------|----------------------|--------------------------------|------------------------|
| 10/525,016  | 07/25/2005  | Yasuhide Nakayama    | SHI-027                        | 5028                   |
| 32628 7590 02/04/2008<br>KANESAKA BERNER AND PARTNERS LLP<br>1700 DIAGONAL RD<br>SUITE 310<br>ALEXANDRIA, VA 22314-2848 |             |                      | EXAMINER<br>STROUD, JONATHAN R |                        |
|   |             |                      | ART UNIT<br>3774               | PAPER NUMBER           |
|   |             |                      | MAIL DATE<br>02/04/2008        | DELIVERY MODE<br>PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/525,016

Applicant(s)

NAKAYAMA ET AL.

Examiner

Jonathan R. Stroud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-21, 23-40 and 42-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-21, 23-40 and 42-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant has cancelled claims 22 and 41 and added claim 78. Claims 1-21 and 23-40 and 42-77 stand rejected under 35 U.S.C. 102(b). Hence, Claims 1-21, 23-40 and 42-78 are pending.

### ***Response to Arguments***

1. Applicant's arguments filed 11/14/2007 with respect to the claim objections and claim rejections under 35 USC 112 have been fully considered and are persuasive. Hence, those rejections have been withdrawn.
2. Applicant's arguments filed 11/14/2007 with respect to the 35 USC 102 (b) rejections of claims 1-2, 5, 7-8, 10-14, 20-22, 25, 26, 30, 51-70 and 72-77 over Dereume 6,165,212 and claims 15, 32, 33, 39, 40, 41 and 44-45 over Edwin 6,245,099, and further the 35 USC 103(a) rejection of claims 3, 4, 6, 9, 16-19, 24, 27-29, 43, and 71 over Dereume, and 34-38 in view of Edwin, and 23, 31 and 42 over Dereume, further in view of Edwin, and claims 46-50 over Edwin, further in view of Dereume, have been fully considered but they are not persuasive.
3. Applicant has amended claims to read "said polymer layers are closely attached to and cover an entire surface of the stent matrix, said polymer layers include a plurality of fine through pores formed, after formation of the polymer layers, at portions where the stent matrix does not exist".
4. Examiner respectfully points out that this does not further limit the claim in view of the prior art, since through pores still exist at portions where the stent matrix does not.

5. Applicant argues that the presence of random pores indicates that the support must have portions not covered by the cover. This seems in direct contrast to his own claimed through pores. If the applicant means to say that there exist pores that expose the support structure, his claim in no way limits against such pores, only positively allows for some pores at locations where they would not reveal the stent support matrix.
6. Applicant seems to argue that in the presence of both the liner and the cover, that pores would not extend entirely through the device. However, in the abstract it is clear that the prior art anticipates a porous cover without a liner, or a porous liner without a cover, which would still fully anticipate applicant's claims. Further, some pores would line up depending on how porous the item is.
7. Further, even if the cover and liner's porous surface do not exhibit through pores, the windows 37, col. 6, ll. 45-52, "can be formed through the cover and/or liner and/or tubular support". This constitutes a plurality of through pores by applicant's definition.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
9. Claim 78 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what the applicant means by the term "smooth". It is a relative term – for instance, a carpet, or a wall, could be considered smooth compared to a jagged edge, but without anything to compare it to, smooth is indefinite.

***Claim Rejections - 35 USC § 102***

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claim 78 is rejected under 35 U.S.C. 102(b) as being anticipated, as best understood (see rejections under 35 U.S.C. 112, second paragraph, above) by Dereume 6,165,212.

12. Dereume discloses a stent as claimed and as discussed above, and further shows embodiments Fig. 2, that are relatively smooth compared to other embodiments of the design. Further, the material used to make the devices could be considered smooth.

***Conclusion***

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN R. STROUD whose telephone number is (571)270-3070. The examiner can normally be reached on Monday through Friday, 7:30 a.m. to 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan R Stroud/  
Examiner, Art Unit 3774

*Thomas V Sweet*  
*Primary Examiner AU 3774*  
*[Signature]*